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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,056	01/02/2004	Gerianne Tringali DiPiano	FEM 104	1945

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,056	DIPIANO ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/12/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election without traverse of Claims 1-9, drawn to a drug formulation comprising a drug in an amount effective to provide relief from diseases or disorders of the breast in a pharmaceutically acceptable carrier for topical administration to the breast, wherein the drug is not a non-steroidal anti-inflammatory or analgesic, classified in class 514, subclasses 176, 648 is acknowledged.

Accordingly, claims 1-9 are being examined and claims 10-19 are withdrawn from consideration since they are non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to **a drug** formulation comprising a drug in an amount effective to provide relief from **diseases or disorders of the breast** in a pharmaceutically

acceptable carrier for topical administration to the breast, wherein the drug is not a non-steroidal anti-inflammatory or analgesic.

Claim 6 depends from claim 1 wherein the drug is selected from **chemotherapeutic agent**, **hormones**, hormone releasing agents, **hormone analogs**, and **anti-proliferative agents**.

Claim 7 depend from claim 6 herein the drug is selected from **antiestrogens** and LHRH a**nalgues**.

The claims thus encompass a broad genus of **a drug** which must have the property of also having relief property of **any diseases or disorders of the breast**.

The instant specification does not describe or exemplify **any drug**, much less any **chemotherapeutic agent**, **hormones**, hormone releasing agents, **hormone analogs**, **antiestrogens**, LHRH **analgues** and **anti-proliferative agents** providing relief from **disease or disorder of the breast.**

This instant specification therefore does not provide a basis for one of skill in the art to envision the structural/functional characteristics of such a compound (**any drug** including **any chemotherapeutic agent**, **hormones**, hormone releasing agents, **hormone analogs**, **antiestrogens**, LHRH **analgues** and **anti-proliferative agents)** and to envision prodviding relief of **any disesease or disorders of the breast.** The premise for the limitation of **a drug** also providing relief of a disorder or disease of the breast appears to be drived from the observation in the instant specification that a particular chemotherapeutic drugs such as danazol, bromocriptine or tamoxifen. (page 7, lines 20-25). The specification does not however, indicate why one should assume

based on this observation that **any drug** would provide relief from **any diseases or disorders of the breast.**

Give the broad of genus of a drug encompassed by the rejected claim, and given the lack of a basis provided by instant specification or prior art to envision **a drug** that are necessary capable of providing relief **from any disease or disorder** of the breast, one of skill in the art would not have been able to envision a sufficient number of a drug **any chemotherapeutic agent**, **hormones**, hormone releasing agents, **hormone analogs**, **antiestrogens**, LHRH **analgues** and **anti-proliferative agents** possessing characteristics of relieving from disease or disorders of the breast broadly claimed genus. Therefore, one of skill in the art would reasonably have concluded Applicants' were not in possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mauvais-Jarvis et al. (U.S.Patent No. 4,919,937).

Mauvais-Jarvis et al. teach **anti-estrogen drug** of 1-[4-(2-N-dimethylaminoethoxy)phenyl]-1(4-hydroxyphenyl)-2-phenylbut-1-(Z)-ene (also known as

4-hydroxytamoxifen) formulated in **aqueous alcoholic gel**. (abstract, claim 1). Mauvais-Jarvis et al. teach that the drug can be administered percutaneously, **preferably topically** to a breast. (column 2, lines 29-32, column 3, lines 13-15, lines 52-57). Mauvais-Jarvis et al. observed that anti-estrogen drug, **4-hydroxytamoxifen**, in 60% strength **alcoholic solution** was applied on the skin overlying cancerous mammary tumors proved capable of passing through the cutaneous barrier and being taking up on the receptor molecules in these tumors. (column 2, lines 13-20). Mauvais-Jarvis et al. teach that the anti-estrogen drug, **4-hydroxytamoxifen,** is useful for trating disease of the breast without harmful side effects. (column 3, lines 52-55). Mauvais-Jarvis et al. illustrate the effective amount **4-hydroxytamoxifen** utilized in a gel formulation. (column 3, table).

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragavan et al. (U.S.Patent No. 5,993,856).

Ragavan et al. teach a micro or nanoparticulate drug formulation for topical administration comprising danazole or anticancer drug, anti-proliferative drug in an effective amount formulated in foams, suspension, solution, ointment and cream. (abstract, claims particularly, claims 31-33, Examples 1-3, column 3, lines 10-15). Ragavan et al. teaches that the microparticle danazol comprises 10mg/day, 25mg/day, 50mg/day. (Example 3). These doages are within and/or overlap Applicant's preferred danzole dosage rage in the specification on page 9, under dosage. Ragavan et al. illustrate 1mg gel formulation comprising microparticulate formulation of danazol in

Examples 1 and 2. Ragavan et al. illustrate that danazole concentrations of 1mg/300g rat were administered and donazole concentrations of 100mg /50kg were administered to women. (table 1). These dosages are within Applicant's dosage range of danazole in the specification page 9.

Applicants' recitation in claims 1 and 9 of an intended use of treating benign diseases of the breast and to relief from disease or disorders of the breast do not represent a patentable limitation since such fails to impart any physical limitation to the composition since the prior teaches same formulation comprising the same active agent with the same "effective amount" as claimed by Applicants.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 31-33 of U.S. Patent No. 5,993,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. The claims in patent teach a micro or nanoparticulate drug formulation for topical administration comprising danazole or anticancer drug, anti-proliferative drug in an effective amount formulated in foams, tablets and creams and same "effective amounts" of treating a diseases or disorder in a regions overlap with instantly claimed "effective amounts" to provide relief from disease or disorders of the breast.

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 17 of U.S. Patent No. 6,652,874 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. The claims in patent teach a drug formulation comprising the drug slected from the group consisting of anticancer drugs, cytotherapeutic drugs, anti-proliferative drugs, and antiviral drugs formulated in micro or naoparticulates with same "effective amounts" of treating a

diseases or disorder in a regions overlap with instantly claimed "effective amounts" to provide relief from disease or disorders of the breast. (see example 3, and instant dosage range in the specification on page 9).

Claims 1-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 of U.S. Patent No. 6,416,778 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. The claims in patent teach a drug formulation including liquid suspension, hydrogel or topical ointment or a cream comprising the drug particles danazole for regional administration of an effective amount to provide relief from symptoms of a disease or disorder with same "effective amounts" of treating a diseases or disorder in a regions overlap with instantly claimed "effective amounts" to provide relief from disease or disorders of the breast. (see example 3, and instant dosage range in the specification on page 9).

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
March 13, 2007